2 510(k) Summary of Safety and Effectiveness

Manufacturer/Sponsor	Arthrex, Inc.1370 Creekside Boulevard Naples, Florida 34108-1945
510(k) Contact	Mariela Cabarcas Regulatory Affairs Associate Telephone: 239/643.5553, ext. 1246 Fax: 239/598.5508 Email: mcabarcas@arthrex.com
Trade Name	Arthrex Bio-Composite Suture Anchors: Arthrex Bio-Composite PushLock, Bio-Composite Tak and Bio-Composite Corkscrew.
Common Name	Suture Anchor.
Product Code - Classification Name	HWC -Screw, Fixation, Bone MBI - Fastener, Fixation, Nondegradable Soft Tissue JDR - Staple, fixation, bone MAI - Fastener, Fixation, Biodegradable, Soft Tissue
Predicate Device	Arthrex PushLock, Tak and Corkscrew Suture Anchors: K061863
Device Description and Intended Use	The Arthrex Bio-Composite Suture Anchors Family is very similar to the predicate devices in diameter, length, and eyelet design. The difference lies in the bio-degradable material used to construct the new model. The implants will use PLLA or PLDLA combined with TCP. The Arthrex Bio-Composite Suture Anchor Family is intended to be used for: • Fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and pelvis. • For suture or tissue fixation in the foot, ankle, hand, wrist, elbow, shoulder, and in select maxillofacial applications where size is appropriate. Please see indications for use statements for specific indications.
Substantial Equivalence Summary	The Arthrex Bio-Composite Suture Anchor Family is substantially equivalent to the predicate Arthrex PushLock, Tak and Corkscrew Suture Anchors families in which the basic features and intended uses are identical except for the exclusion of the hip indication. The Bio-Composite Suture Anchors are not indicated to be used for the capsular and acetabular labral repair. Any differences between the *Bio-Composite Suture Anchor Family* and the predicate K061863 are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the new *Bio-Composite Suture Anchor Family* is substantially equivalent to the currently marketed predicate device.

3 Substantial Equivalence

The fundamental scientific technology of the Arthrex Bio-Composite Suture Anchors has not changed from the previously cleared Suture Anchor Family, K061863.

The indications for use of the Arthrex Bio-Composite Suture Anchors remain the same as those cleared for the predicate PushLock, Tak, Corkscrew Suture Anchors (K061863) except for the exclusion of the hip indications. The Bio-Composite Suture Anchors are not indicated to be used for the capsular and acetabular labral repair.

The Bio-composite Suture Anchors have been developed using different biodegradable materials such as Poly (L-Lactide) (PLLA) and (PLDLA) Poly L-co-D-L-Lactide and ceramic material TriCalcium Phosphate (TCP). The biodegradable materials of the Bio-Composite Suture Anchors are currently used in the manufacturing of numerous Arthrex marketed bioabsorbable devices. The composite materials used in the construction of the Bio-Composite Suture Anchors have a long history of implantable use in the medical field and have been shown to be biocompatible.

The Arthrex Bio-Composite Suture Anchor family is substantially equivalent to the predicate device Suture Anchor family from K061863, where basic features and intended uses are the same. Any design differences between the Arthrex Bio-Composite Suture Anchors and the original Family of Suture Anchors are considered minor and do not raise questions concerning safety and effectiveness.

Based on the information submitted, Arthrex has determined that the Bio-Composite Suture Anchor Family is substantially equivalent to the cleared Suture Anchor Family, K061863.

Refer to *Table 9-1* for a comparison of the similarities and differences between the cleared Arthrex Suture Anchors (K061863) and the new devices, the Arthrex Bio-Composite Suture Anchors.

Table 3-1 A comparison of Cleared Suture Anchor Family and the new Bio-Composite Suture Anchor Family.

Similarities and Differences	Arthrex Bio-Composite Suture Anchors *This "Special" Submission*	Arthrex PushLok, Tak, and Corkscrew Suture Anchors *CLEARED, (K061863)*
Product Code	MAI, HWC	HWC, MBI, JDR, MAI
21 CFR	888.3030 888.3040	888.3040 888.3030
Design	Screw-In, push-In Anchors: Full threaded, cannulated/ non-cannulated, partially cannulated, with or without suture eyelet.	Screw-In, push-In Anchors: Full threaded, cannulated/ non- cannulated, partially cannulated, with or without suture eyelet.
Material	PLLA/TCP or PLDLA/TCP	PLLA, PLDLA, PEEK, Titanium
Intended Use	Identical	Identical
Indications for Use	Identical except for the exclusion of the hip indications.	• Fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, hip, knee, hand/wrist, elbow, and pelvis. • For suture or tissue fixation in the foot, ankle, hip, hand, wrist, elbow, shoulder, and in select maxillofacial applications where size is appropriate.
Diameter	3 – 5.5 mm	2.4 - 6.5 mm
Length	14 – 14.7 mm	5 – 18.5 mm
Threaded	Yes	Yes
Sutures	Insert molded and supplied with, or recommended Suture. Polyblend	Insert molded and supplied with, or recommended Suture. Polyblend
Packaging	Identical	Identical

Sterile	Yes	Yes
Shelf Life	2 years	2 years- PLLA, PLDLA 5 years- PEEK and Ti
Single Use	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2007

Arthrex, Inc.
% Ms. Mariela Cabarcas
Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K071177
Trade/Device Name: Arthrex Bio-Composite Suture Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MBI, JDR, MAI
Dated: June 5, 2007
Received: June 6, 2007

Dear Ms. Cabarcas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or 240-276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson 6/29/07

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 Indications for Use Form

Indications for Use

510(k) Number: K071177

Device Name: **Arthrex Bio-Composite Corkscrew**

The **Arthrex Bio-Composite Corkscrew** is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and pelvis in, but not limited to, the following procedures:

Shoulder:	Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.
Foot/Ankle:	Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot reconstruction, Metatarsal Ligament Repair/Tendon Repair, Bunionectomy.
Knee:	Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis.
Hand/Wrist:	Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction.
Elbow:	Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial collateral Ligament Reconstruction, Lateral Epicondylitis Repair.
Pelvis:	Bladder Neck Suspension for female urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency.

Prescription Use _X_ AND/OR Over-The-Counter Use No

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071177

Indications for Use

510(k) Number: K071177

Device Name: **Arthrex Bio-Composite PushLock™**

The **Arthrex Bio-Composite PushLock™** is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and pelvis in the following procedures:

Shoulder:	Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.
Foot/Ankle:	Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair, Bunionectomy.
Knee:	Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis.
Hand/Wrist:	Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction.
Elbow:	Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair.
Pelvis:	Bladder Neck Suspension for female urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency.

Prescription Use __X__ AND/OR Over-The-Counter Use No

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number: K071177

Device Name: **Arthrex Bio-Composite Tak**

The **Arthrex Bio-Composite Tak™** is intended to be used for suture or tissue fixation in the foot, ankle, knee, hand, wrist, shoulder, elbow, and in select maxillofacial applications. Specific indications are listed below and are size appropriate per patient needs:

Skull:	Stabilization and fixation of oral cranio-maxillofacial skeletal bone, mandible and maxillofacial bones, Lateral Canthoplasty, Repair of Nasal Vestibular Stenosis, Brow Lift, Temporomandibular Joint (TMJ) reconstruction, Soft tissue attachment to the parietal temporal ridge, frontal, zygoma, and perioorbital bones of the skull.
Elbow:	Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.
Shoulder:	Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.
Hand/Wrist:	Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of Collateral Ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, Digital Tendon Transfers.
Foot/Ankle:	Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus Reconstruction, Digital Tendon Transfers, Mid-foot reconstruction.
Knee:	Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis.
Pelvis:	Bladder Neck Suspension for female urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency.

Prescription Use _X_ AND/OR Over-The-Counter Use No

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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